



U.S. Military Immunization Program: *State of the Program*

Science - Quality - Care - Confidence

**Information briefing to
Armed Forces Epidemiological Board
*24 May 2006***

COL John D. Grabenstein, RPh, PhD
Director, Military Vaccine Agency
U.S. Army Medical Command



Military Vaccine (MILVAX) Agency



Mission: To enhance readiness and protect health, by:

- synchronizing information,
- delivering education,
- enhancing understanding,
- promoting quality, and
- coordinating military immunization programs worldwide.

“...I have a message for our military: Be Ready.”

President George W.

Bush

20 Sep 01



Agenda

- **Perspective**
- **Anthrax**
- **Smallpox**
- **Influenza**
- **Vignettes:**
 - **Meningococcal conjugate**
 - **Pertussis—adult (Tdap)**
 - **Mumps**
- **Administrative Issues**
- **Education & Quality Initiatives**



Immunization to Protect the U.S. Armed Forces: Heritage, Current Practice, Prospects

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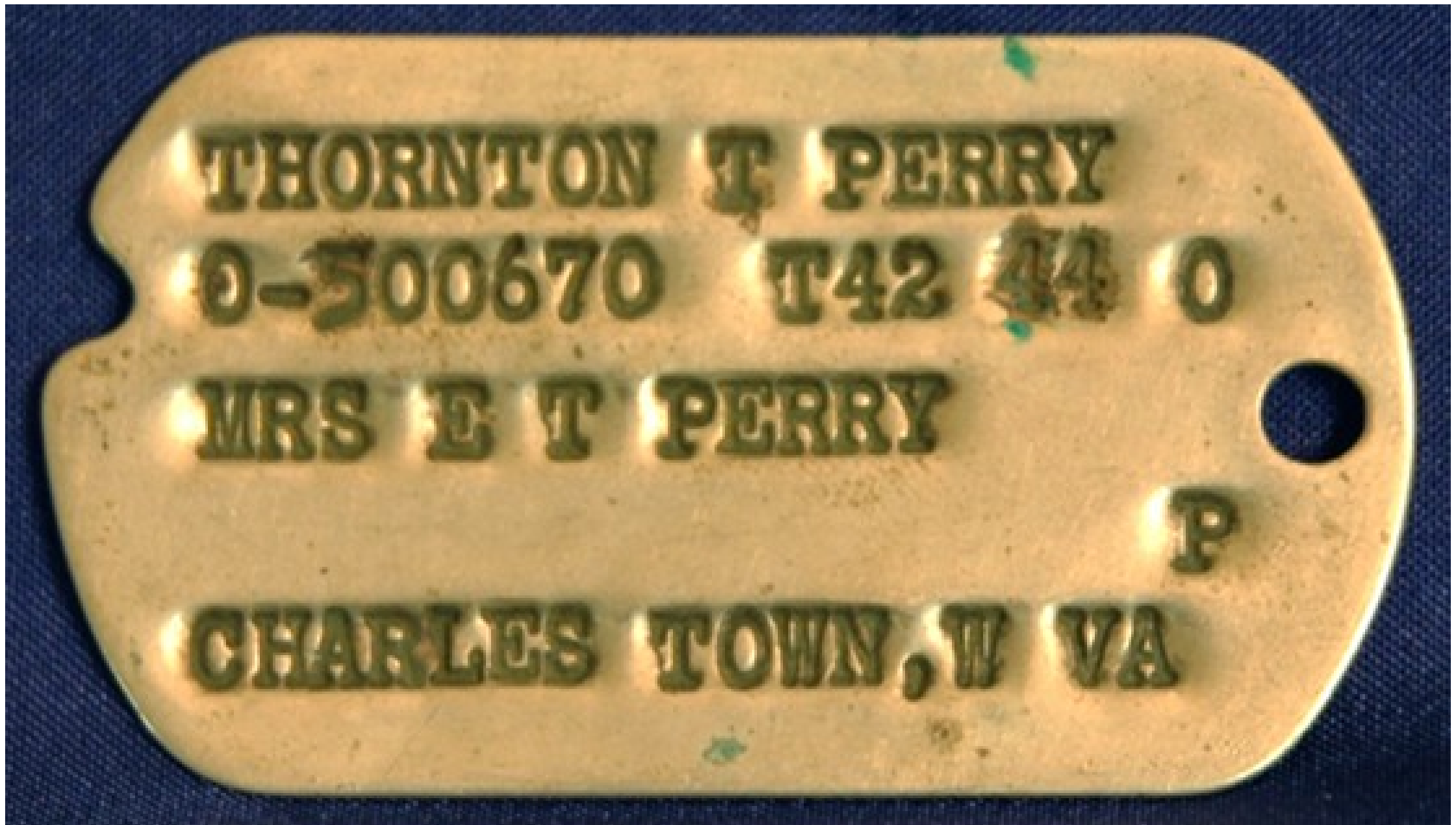
Allergy-Immunology Dept, Vaccine Healthcare Ctrs Network, Walter Reed Army Medical Center, Washington, DC

Abstract

Americans serving with the U.S. Armed Forces need protection from dangerous infections they can contract during training, based on occupation, during overseas deployment, or because of underlying health status. For over 230 years, the military healthcare system has immunized troops to protect them personally and help them accomplish their missions. Military researchers have invented, developed, and improved vaccines and immunization delivery methods against more than 20 diseases. This article consolidates content from several previous historical reviews, adds additional sources, and cites primary literature regarding military contributions and accomplishments. Discussion emphasizes smallpox, typhoid fever, tetanus, influenza, meningococcal disease, adenovirus, yellow fever, pneumococcal disease, and anthrax. Delivery issues include documentation, simultaneous immunization, sero-screening, safety surveillance, jet injection, and cold-chain management. Immunization policies for each major U.S. conflict are described. Military immunization programs need to be individualized based on personal contraindications and prior immunity. The proper conduct of military immunization programs respects the need for detailed education of military personnel, maximizes quality in immunization delivery, and supports quality clinical care to prevent and treat adverse events after immunization. Military immunization programs maintain the health of soldiers, marines, sailors, airmen, and coast guardsmen, the resources most critical to military success.

An abridged version of this manuscript has been accepted for publication in *Epidemiologic Reviews*.

- **1941 - US Army authorizes tetanus toxoid for troops, stamped on ID**



2003 *TIME* PERSON OF THE



Joe Raedle / Getty Images





**In
press !**

Medical Services

Immunizations and Chemoprophylaxis

**Army Regulation 40-562
BUMEDINST 6230.15
Air Force Instruction 48-110(I)
CG COMDTINST M6230.4F**

**Department of the Army
Bureau of Medicine
Air Force
Coast Guard**

This publication supersedes Army Regulation 40-562/BUMEDINST 6230.15/Air Force Instruction 48-110(1)/CG COMDTINST M6230.4E dated 1 Nov 1995.

Unclassified



- Your health and safety are our #1 concerns.
- The anthrax vaccine is safe and effective.
- The threat from anthrax is deadly and real.
- Vaccination offers a layer of protection in addition to antibiotics and other measures needed for certain members of the Armed Forces.





Anthrax Vaccine Immunization Program

- **Legal / Regulatory Situation:**

- Judge deemed AVA not indicated for inhalation anthrax, remanded Jan 04 final rule to FDA, lacked public comment
- SECDEF, 27 Oct 04: full stop
- FDA conducts 90-day comment period, Dec 04 – Mar 05
- DoD requests, FDA issues EUA, 6-dose pre-exp, 27 Jan 05
- FDA issues Final Order 19 Dec 05. EUA expires 14 Jan 06
- Anthrax vaccinations continue, policy under review
- Mar 98 to May 06: 5.5 million doses to 1.5 million people

- **Program Issues:**

- BioPort production steady, inventory accumulating
- 26 published articles + IOM report, www.anthrax.mil/safety
- Due out: vision study, flight physical exams, longer TAIHOD



Anthrax Vaccine and Risk of Optic Neuritis

U.S. Military, 1998-2003

VAU: CDC scientists, with DoD & FDA

collaboration

- First-time diagnosis of optic neuritis, ICD9 377.30, 377.31, 377.32, 377.39
- Jan 1998 through Dec 2003
- Matched on gender, deployment, and component (Active, Reserve, Guard)

- Multivariable conditional logistic regression (n=4,524) for optic neuritis by vaccines received within 6-, 12-, and 18-week intervals

Vaccine	6-week observation OR	6-week observation 95% CI	12-week observation OR	12-week observation 95% CI	18-week observation OR	18-week observation 95% CI
Anthrax	1.18	(0.74, 1.87)	0.92	(0.63, 1.35)	0.81	(0.58, 1.14)
Smallpox	0.71	(0.22, 2.33)	0.66	(0.25, 1.73)	0.83	(0.37, 1.85)
Hepatitis B	0.67	(0.31, 1.46)	0.95	(0.57, 1.58)	1.02	(0.68, 1.54)
Influenza	1.01	(0.71, 1.46)	1.26	(0.95, 1.67)	1.01	(0.79, 1.29)

Presented to American Public Health Association by Daniel Payne, PhD, MSPH, Charles Rose, Jr., PhD, 13 Dec 05; Manuscript accepted by Archives of Neurology



Smallpox Website - www.smallpox.mil

MIL VAX - Microsoft Internet Explorer



File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media Print View Source Reload

Address <http://www.smallpox.army.mil>

THE DANGER

THE VACCINE

THE PRIORITY

THE STRATEGY

adverse event info

education toolkit

resource center

SMALLPOX VACCINATION PROGRAM

[contact us](#)



- Smallpox is contagious, deadly, and would disrupt military missions.
- Smallpox vaccine prevents smallpox and we will use it carefully.
- Preserving the health and safety of our people is our top concern.
- The Defense Department's smallpox vaccination program is part of our national strategy to safeguard Americans against smallpox attack.

MIL VAX

[DoD Begins Smallpox Vaccination Program](#)

[SVP Online Proficiency Training](#)

[DoD's Smallpox Vaccination Lessons Learned](#)

[MM](#)

[http://
www.smallpox.mil](http://www.smallpox.mil)

Last Updated 01/24/2003



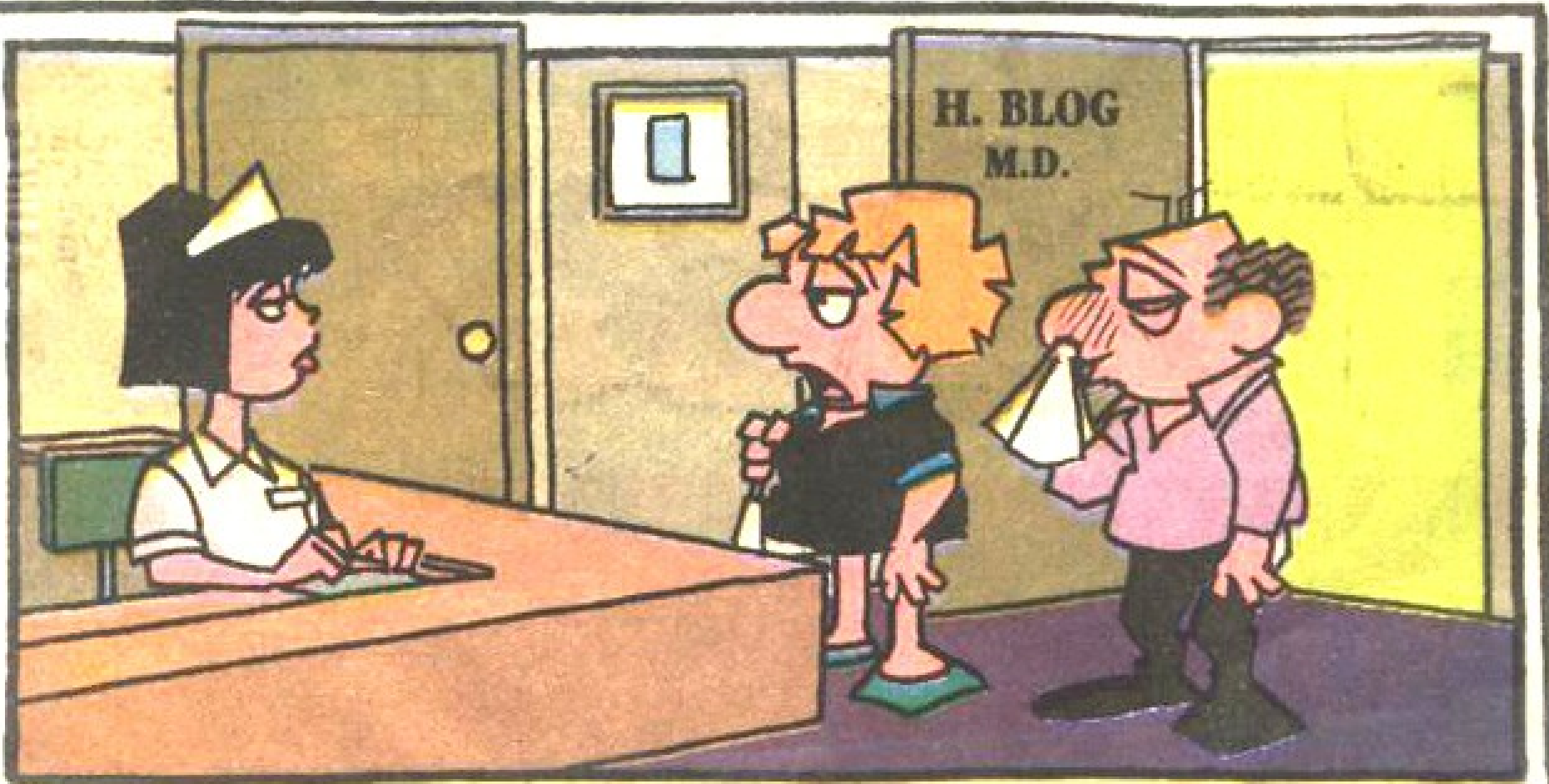
DoD Smallpox Vaccination Program ***as of 10 May 06***

- **Response teams, hospital workers, operational forces**
 - **Screened: 1,090,000 - Vaccinated: 1,009,645**
 - **Primary: 71% - Male: 88%**
- **Exemption process working well**
 - **Eczema vaccinatum— 0 — Progressive vaccinia— 0**
- **Education working well, but we can do better**
 - **Autoinoculation—86**
 - **Contact transfer vaccinia—56: “Don’t let guard down at home.”**
 - **Family— 23, intimate— 20, friend— 13, patient— 0**
 - **Peri-vaccination Pregnancy—75% undetectable**
- **VIG treatments more rare than expected: Burn— 1, eye— 2**
- **Encephalitis— 1**
- **Myo-pericarditis—117: Suspect— 22, probable— 90, confirmed— 5**
- **Deaths: Possible— 1 (lupus-like illness) Unrelated— 6**
- **Derived from 1,797 VAERS reports and other sources**



ACIP - AFEB Smallpox Vaccine Safety Working Group

- Dec 02 – Jun 04 report in preparation for publication
- Neurologic events report published in *JAMA*
- Prognostic study of myocarditis patients being written by Vaccine Healthcare Centers.



"MR. I-DON'T-BELIEVE-IN-FLU-SHOTS IS HERE."

"There are 1,440 minutes in a day. When I tell you there were 1,440 admissions in a day, you will realize the strain put on our Nursing and Medical force."

-Leonard Wood, fall 1918



Emergency hospital during **influenza** epidemic, Camp Funston, Kansas, 1918



Influenza Immunization Issues

- Seasonal Influenza Immunization Policy
 - Continue to protect the force
 - Widen recommendations for beneficiaries a la ACIP
 - In consultation: requirement for civilian healthcare workers at DoD MTFs
- Pandemic Influenza Preparedness
 - A/H5N1 vaccine: DoD purchased 2.43M doses @ 90 mcg from Sanofi Pasteur, based on 2004 virus from Vietnam (“1203 vaccine”)
 - 1.3M doses to be bottled
 - Remainder stored in bulk pending adjuvant trials, Jul 06
 - Concept: begin immunization of select personnel at WHO Phase 4
 - HHS commissioned pilot lot of clade-2 vaccine (Indonesian strain)
 - Scientific convention holds that H5N1 vaccine may prime immune system (dose 1 of 2), but not known for sure
- Other Pandemic Issues – Coming up next...



Meningococcal Vaccines

- Meningococcal A/C/Y/W-135 protein-conjugate vaccine, *Menactra*, Sanofi Pasteur, licensed 17 Jan 05
- Presumably superior duration of protection
- ACIP recommends for 11 & 15 y/o, college
- JPMPG: Services to substitute *Menactra* for *Menomune* asap, given that *Menomune* will be phased out eventually.
- Logistics: ***Menactra* shipping to DoD sites largely suspended during national shortage**



Pertussis Immunization

- Acellular pertussis vaccine for adults and adolescents, as Tdap
- Pertussis in adults (prolonged cough illness ~ 0.4% to 1.5% per year), adults as vectors to children (indirect)
- *Adacel*, Sanofi Pasteur, 11-54 y/o
- *Boostrix*, GlaxoSmithKline, 10-18 y/o
- ACIP recommends @ age 11 and routine booster doses (sooner intervals acceptable)
- JPMMPG: Services to substitute Tdap for Td asap.
- Logistics: **Tdap now shipping to DoD sites.**



Mumps

- Midwestern US, outbreak of > 1,000 reported cases of mumps.
- Military public health officials detected usual (small) amount of mumps cases at military clinics and hospitals.
- Within DoD, no need for extraordinary efforts. Simply follow existing policies. For example, accessions given MMR vaccine (or blood test).
- Effectiveness of MMR vaccine against mumps is ~ 80% after 1 dose and ~ 90% after 2 doses.
- In brief, CDC mumps recommendations for civilians:
 - Give children first MMR at 12 to 15 mon, second dose at 4 to 6 y.
 - Else give second MMR by 11- to 12-year-old visit.
 - Adults born before 1957 assumed immune by natural infection.
 - Give adults born in 1957 or later at least 1 dose of MMR vaccine during their lifetime. A second dose recommended for
 - 1) Those recently exposed in an outbreak setting;
 - 4) Students in postsecondary educational institutions;
 - 5) Those who work in a health-care facility; or
 - 6) Those who plan to travel internationally.



Adenovirus Vaccine

- **Adenovirus Vaccines Type 4 and Type 7**
 - Manufacturing Status
 - Lyophilizer validation
 - **Clinical Trial Status**
 - Phase 1 trial: Well **tolerated**.
 - **Phase III trial, target Sep 06:**
 - Protocol at IRBs
 - Fort Jackson and Great Lakes NRTC
 - FDA:
 - Increase enrollment to 4,000 volunteers
 - Meeting Jun 06
 - Detailed update planned for Sep 06 AFEB meeting



Multiple, Near-Concurrent Vaccinations (MNCV) and U.S. military hospitalizations

Daniel Payne, Aaron Aranas, M. M. McNeil, S. Duderstadt, Charles Rose, Jr.

Design: Cross-over cohort design contrasting hospitalizations, 120-day post-MNCV interval vs. 120-day pre-exposure interval. Cox proportional hazards model. Jan 98 through Dec 03. MNCV among 19,743 persons analyzed, 195 hospitalized in post-MNCV interval, 215 in pre-exposure interval.

Results: 2+ MNCV $RR = 0.90$, 95% CI = 0.74, 1.10.

For 3 MNCV, $RR=0.86$ (0.58, 1.29). For 4 MNCV, $RR=1.08$ (0.66, 1.76).

For 5+ MNCV, $RR = 0.84$ (0.48, 1.48).

Conclusions: MNC vaccinations not statistically significantly associated with increased hospitalization risk from large sample of U.S. Military personnel.

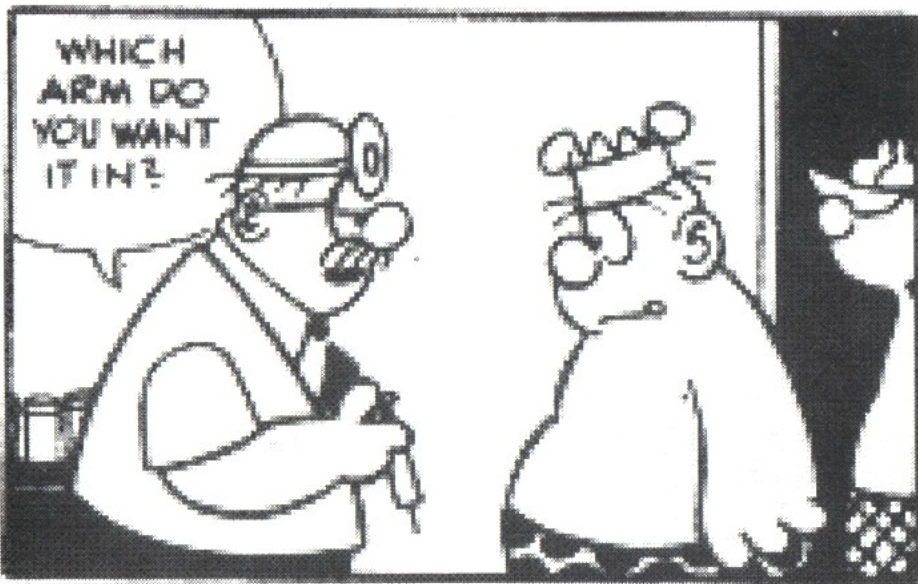
Presented with American Hospitalization Association 123rd Annual Meeting, Daniel Payne, PhD, MSPH, Charles Rose, Jr., PhD, 13 Dec 05



Vaccine Healthcare Centers (VHC)

Recent Accomplishments:

- Support and enhance DoD reports to VAERS
- Maintain and analyze myopericarditis registry
- Develop secure web-based consultation system (AskVHC)
- Provide case management of adverse events after immunization, acute or chronic
- Coordinate IRB-approved research protocols
- Coordinate education efforts for DoD healthcare providers in adverse-event management, based on clinical experience



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Search

All About Japanese Encephalitis



The report provides updated recommendations to improve prevention of perinatal and early childhood HBV transmission, including implementation of universal infant vaccination beginning at birth, and to increase vaccine coverage among previously unvaccinated children and adolescents.

[more...](#)

**Recommended Adult
Immunization Schedule --
- United States, October
2005--September 2006**

[more ...](#)

The Advisory Committee on Immunization Practices (ACIP) annually reviews the recommended Adult Immunization Schedule to ensure that the schedule reflects current recommendations for the use of licensed vaccines. In June 2005, ACIP approved the Adult Immunization Schedule for October 2005–September 2006. This

Have fun learning about vaccines and vaccine preventable diseases with our monthly crossword puzzle, brought to you by Immunization University.

[more...](#)

DoD Pandemic Influenza Resources





Friday, May 05, 2006 5:23:04 PM ET

Search

[quick reference](#) | [contact us](#) | [site map](#)

IMMUNIZATION UNIVERSITY



Welcome

We welcome healthcare workers to the DoD Immunization University, sponsored by the Military Vaccine Agency. We are committed to making this the most fruitful single location to access to a wide range of training products relating to immunization services.

*Don't reinvent the wheel,
learn from those around
you...*

[Home](#)

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Event](#)

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[Crossword Puzzles](#)

[Imz Basic Course](#)

[Imz Leaders
Course](#)

[Project Immune
Readiness](#)

[Smallpox
On-line Training](#)

What is Immunization University?

An informal collection of guidelines and training resources to help staff make every immunization an excellent one. Designed to enhance the skills of healthcare workers from a variety of professional and paraprofessional backgrounds, "Immunization University" offers training on vaccine products and immunization services through distance learning and on-site classes.

How do I find out more?

The core elements of Immunization University are available at the list on the left side of your screen. Additional tools and courses will be added over time. Please sign up for our list-serv which will also include updates as they become available. You may also check back to this page regularly for the latest information on Immunization University.

Join Immunization University List-serv

First Name:

Last Name:

E-Mail Address:

www.vaccines.mil/Im



DoD Immunization Standards

In revised joint instruction: Immunization and Chemoprophylaxis, AR 40-562 / BUMEDINST 6230.15 / AFI 48-110(I) / CG COMDTINST M6230.4F

1. Immunization availability
2. Information and education before immunization
3. Vaccine storage and handling
4. Indications & contraindications to immunization
5. Immunization record keeping
6. Training
7. Adverse events after immunization
8. Vaccine advocacy to protect the military family

Adapted from National Vaccine Advisory Committee. Adult immunization programs in nontraditional settings. *MMWR* 2000;49(RR-1):1-13.
<ftp.cdc.gov/pub/Publications/mmwr/rr/rr4901.pdf>



6-Sided Training Folders

Vaccines · Diseases

Resource Center

Education Toolkit

Adverse Events

Imz University

Imz Leaders Course

Anthrax & Smallpox

On-line Training

Project Immune

Readiness

Clinic Quality

Improvement Program

Personal Competency
Assessment File

CE Credit

Crossword Puzzle



What is the Personal Competency Assessment File (CAF)?

A CAF is used as a repository for information related to individual competence for all non-privileged healthcare personnel with patient contact and is a great way to keep track of training completed specific to their duty position. Maintaining CAF's for all healthcare individuals facilitates documentation of the training portion required in the soon to be released joint directive on Immunizations and Chemoprophylaxis (AR 40-562, AFJ 48-110, BUMEDINST 6230.50, CG COMDTINST M6230.4F). Army Regulation 40-68, [Clinical Quality Management](#) (AFI 44-119, AFI 36-2201v3, NAVMEDCENS DIEGO 1872) describes who should have a Competency Assessment File (CAF), what a CAF contains and how to organize the file itself. MILVAX is incorporating examples of the CAF and its contents as part of the Immunization University.

Why should a CAF be used?

JCAHO requires that an annual report elaborate on the levels of competency for all Medical Treatment Facility (MTF) staff.

Army, Air Force and Navy all have regulations requiring competency assessment for all medical professionals and paraprofessionals. Each MTF and support clinic will have in place a mechanism to assess the competence of staff and to identify training needs in accordance with service regulations related to clinical quality management.

The CAF is utilized throughout an individual's assignment or employment. It is hand carried by non-privileged professional (military/civilian) from one place of duty to the next. Privileged healthcare provider's credentials are maintained in either the provider credentialing file (PCF) or provider activity file (PAF) and will be electronically transferred from one facility to the next.

When should the CAF be used and updated?

Competencies will be assessed for para-professionals upon arrival at an MTF and annually thereafter, keeping in mind that all licenses and certifications should be up to date at all times.

How can I download the Personal Competency Assessment File & Instructions?



-- P-CAF Instructions 15 Aug 05



-- CAF 6-sided Folder Coversheets 15 Aug 05

Examples: Competency Assessment Files

INITIAL COMPETENCY ASSESSMENT

Andrew Rader U.S. Army Health Clinic, Fort Myer, VA: FluMist Administration

Patient Population Served: ☐ School Age (9-12) ☐ Adolescents (13-17) ☐ Adults (18-49)

Employee Name: _____ Assessment Start Date: _____ Completion Date: _____

Required Competency or Skill	* Self Assess	Orientation (Preceptor initials & date)	+ Eval Method	Competency Validated by Supervisor (Signature & date)	Comments/Additional Resources
Patient Care Procedures for LPNs and RNs	CRITICAL THINKING: Recognizes unique needs of patients of age groups 9-49 and performs FluMist administration accordingly. Gathers age and diagnosis appropriate supplies and equipment. Explains all procedures in an age appropriate manner according to the level of understanding of the child and the parent/guardian. Approaches child in non-threatening manner and comforts at completion.				
A. Understands the actions, implications, precautions and age groups for administration of FluMist:					
(1) Information sheet read and signed					
(2) Clinic policy regarding children under age 18 must be accompanied by parent or legal guardian					
(3) Familiarity with CDC FluMist handout and MedImmune medication information					
(4) Provides patient VIS (Vaccination Information Statement) sheet to read					
(5) Documentation of Lot Number					
(6) Viewed MedImmune administration video					
B. Understands importance of the care and handling of FluMist Live virus					
(1) Must keep frozen until use					
(2) Must be used within 60 hours (refrigerated)					
(3) May be defrosted by holding in palm of hand and supporting plunger					
(4) Gloves and washes hands between each procedure					
C. Demonstrates proper technique for administration of FluMist					
(1) Remove rubber tip protector					
(2) Patients sits upright, head back, tip inside nostril, depress plunger					
(3) Pinch and remove dose divider clip					
(4) Insert remaining FluMist into other nostril and depress					
(5) See back for diagrams/pictures					
D. Demonstrates ability to recognize signs and symptoms and react to a patient experiencing an anaphylactic reaction					
(1) Positions patient on a litter in treatment room					
(2) Monitors vital signs					
(3) Assesses breathing					
(4) Calls for assistance and administers epinephrine					

* Self Assessment:

1 = Experience
2 = Needs Practice/Assistance
3 = Never Done

+ Evaluation/Validation Methodologies:

T = Tests
D = Demonstration/Observation
V = Verbal

Clinical Skills Reference:

The Lippincott Manual of Nursing Practice
Lippincott-Raven Publishers
Sixth Edition, 1999



Clinic Quality Improvement

	Clinic Self-Assessment Program			
	date:			
#	Topic	Response	Comment	Tools, References, Resources
1	Immunization Availability			
	What are your usual hours of operation? Which days of the week			
2	Information and Education			
a.	Show me the VISs you give to troops and beneficiaries.		If clinic personnel cannot show you these forms, it indicates need to either gather them or educate staff member on where the forms are located. Forms can be photocopied for distribution or laminated and placed on bulletin board.	http://www.cdc.gov/nip/publications/VIS/default.htm
3	Storage and Handling			
i.	What does your SOP say about Mass vaccination? What does it say about pre-drawing of vaccines into syringes and storage during the vaccination process?		Pre-drawing is not preferred, but can be done if certain conditions are met	http://www.usamma.army.mil anthrax/info.htm
4	Indications and contraindications to immunization			
			How do you feel today? Have you had prior adverse	http://www.immunize.org/catg

smallpox

Medical Logistics: Smallpox Vaccine Distribution

Angiscript



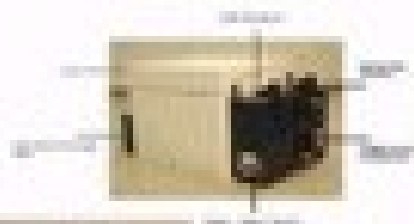
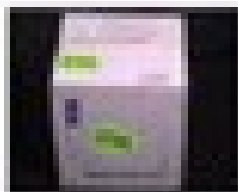
Paused

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XXXXXXXXXXXX

The road that the manufacturer's located on is called Buckeye Lane in Phoenix, Arizona. I had you tell, I want to visit them. The EndureTherm box with specific packing protocols, specific packing protocols developed for the space and the box and different methods.

Equipment Used to Support Cold Chain Distribution



Next / Previous Slide

XXXXXXXX

- 18:00: [Key Temperature Points under U.S. Pharmacopeia Standard](#)
- 18:00: [Key Aspects of Cold Chain Distribution](#)
- 18:00: [Equipment Used to Support Cold Chain Distribution](#)
- 18:00: [Final Inspection of Products](#)

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Project Immune Readiness

IMMUNE READINESS LMS

Version 1.3

Wednesday, September 22

[:: Back](#) [:: Contact](#)

Welcome

John D. Grabenstein
Learner

[Logout](#)

- ❖ Welcome
- ❖ About Immune Readiness
- ❖ Goals and Objectives
- ❖ Target Audience

❖ Courses

- ❖ Other Resources Under Development
- ❖ Credit Information
- ❖ Transcripts
- ❖ Profile
- ❖ Change Password
- ❖ Acknowledgements
- ❖ Disclaimer
- ❖ VHC (Vaccine Healthcare Center)
- ❖ Privacy

AVAILABLE COURSES

Anthrax	Haemophilus Influenzae type b (HIB)	Hepatitis A
Hepatitis B - Advanced	Hepatitis B - General	Influenza
Introduction to Vaccination	Japanese Encephalitis	Measles
Meningococcal	Mumps	Pneumococcal
Polio	Rabies	Rubella
Smallpox Disease	Smallpox Administration	Smallpox Vaccine
Typhoid	Vaccine Storage and Handling	Varicella
Yellow Fever		

[Take a Course](#)

>50 seat hours of CE credit:

<http://www.vhcinfo.org>

<http://www.projectimmunereadiness.amedd.army>



VHC Immunization Tool Kit



**To order, email
askvhc@na.amedd.army.
mil**

2nd edition, 2004

3rd edition, 2005

4th edition, April 2006

**[www.vhcinfo.org/quality_ring.
htm](http://www.vhcinfo.org/quality_ring.htm)**



**Adult, Military
and Childhood
Immunizations**



DEVELOPED AND DISTRIBUTED BY



**WALTER REED NATIONAL
VACCINE HEALTHCARE CENTER**

REVISED OCTOBER 2003



Care for Vaccinated People

Care:

- Ongoing education of health-care providers & medics
- Clinical excellence
- Asking about vaccinations during follow-up care
- Reporting adverse events (VAERS)
- Keeping an open mind (science):
 - Myocarditis due to smallpox vaccine – yes
 - Heart attack due to smallpox vaccine – no
- Vaccine Healthcare Centers (VHC) Network
 - www.vhcinfo.org, askvhc@amedd.army.mil
- Clinical Guidelines for Managing Adverse Events after Vaccination
 - www.vaccines.mil/documents/564acg040909.pdf
- Exemptions as clinically warranted



- **Military Vaccine Agency, Army Surgeon General's Ofc**

- Websites: **www.smallpox.mil,
www.anthrax.mil,
www.vaccines.mil**
- Toll Free: **877.GET.VACC or DSN 761.4245**

- **DoD Vaccine Clinical Call Center:
866.210.6469**

- **Vaccine Healthcare Centers (VHC) Network:
202.782.0411; DSN 662.0411 (www.vhcinfo.org)**

- **Military Medical Treatment Facility (MTF)-OR-if Reserve Component seeking care at a civilian facility, contact the Military Medical Support**



MILVAX Agency: To Do List

Values

**Science - Quality - Care -
Confidence**

To Do List

- Publish correspondence course
- Adopt certification exam
- Enhance web-based training and exchange
- Release videos and posters
- Enhance Vaccine Monitoring System
- Develop flight physical exam dataset
- Implement Accession Screening & Immunization Program
- Support ACIP in revising anthrax guidelines
- ... and much more ...

Guidons

Timely, expert, reliable support to senior leaders.

All immunizers certified or in training.

People get timely, reliable info.

Each immunization an excellent one
Exemption if warranted

All the follow-up care needed

Conserve the fighting strength

Bring troops home safe and healthy.

Keep learning more about vaccines,
how they work, how people
perceive them.

Potent vaccine where its needed
most.

Don't reinvent the wheel.

Bring it all together in one place.

Read the original document(s).



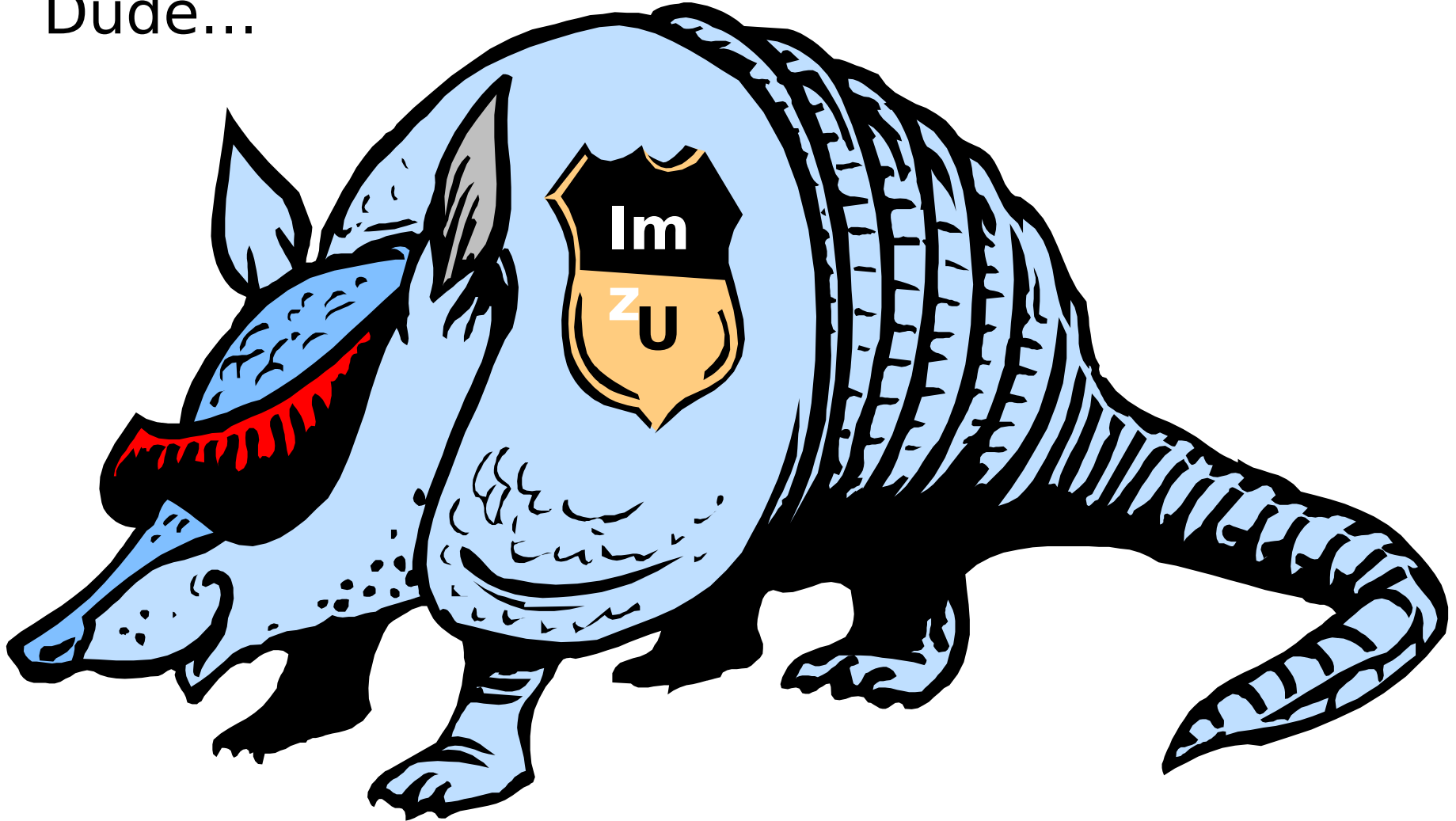
Excellence in immunization requires:

- **Reliable science, published, with eyes & ears remaining wide open.**
- **Quality in shots given, exemptions granted, vaccines used, documents maintained.**
- **Care, in vaccinating and in follow-up, regardless whether vaccine caused problem or not.**
- **Thus earning the confidence of the troops and their families, with mutual understanding.**

Give your best



Dude...



...put your body armor on the insio



Regulatory Status of Medications (eg,

- **Approved (drugs) or Licensed (vaccines): Federal Food Drug & Cosmetic Act or the Public Health Service Act**
 - Standard situation
- **“Off-label” use of approved drug**
 - FDA does not regulate practice of medicine
 - Department cannot rely on this for corporate stance
- **Investigational New Drug (IND) exemption from Federal Food Drug & Cosmetic (FD&C) Act**
 - Status during clinical trials (21 CFR 312)
 - For force protection, must follow 10 USC 1107, EO 13139, 21 CFR 50.23(d), DoD Directive 6200.2
 - Requirements: IRB review, educate, *consent*, document, monitor
- **Emergency Use Authorization (EUA)**
 - 21 USC 360bbb-3, www.fda.gov/opacom/laws/fdcact/fdcact5e.htm
 - If counter CBRN agents or affect national security



Regulatory Status of Medications (eg,

Scenario:

Options to use influenza vaccine formulation intended for southern hemisphere.

Background:

- a. WHO issues two sets of recommendations for influenza vaccine formulae each year,
 - One for northern hemisphere, other for southern hemisphere.
 - Often the same, but not always.
 - When antigens change, one of the hemispheres changes first.
- b. FDA-licensed influenza vaccine for northern hemisphere expires 30 Jun each year
 - In large part to clear refrigerators before new formula shipped.



Influenza Vaccine for Southern

- **Licensed vaccine under Food Drug & Cosmetic Act**
 - Not currently licensed
- **“Off-label” use of approved drug**
 - Practitioners could use influenza vaccine beyond 30 June, but antigenic match may be inappropriate
 - Goes against norm of observing expiry date
- **Use of Unlicensed Vaccine Under IND**
 - Does clinical benefit outweigh paperwork burden ?
- **Emergency Use Authorization (EUA)**
 - Seasonal flu in southern hemisphere doesn't affect national security
- **Licensed vaccine under Food Drug & Cosmetic Act**
 - Specially contract with FDA-licensed facility to produce southern formulation and request FDA license under “strain change” rationale
 - Cost per dose? Other customers (eg, DoS)?